

REMARKS

Information Disclosure Statement

The Office stated that it failed to receive a copy of the 31 documents cited in the Information Disclosure Statement filed April 3, 2002. (Final Office Action at ¶ 2.) Further to the undersigned representative's telephone conversation of November 1, 2006, with Supervisory Examiner Terry McKelvey, Applicants understand that the Examiner has received and will consider these documents that were originally submitted April 3, 2002. Applicants enclose copies of the date-stamped postcard showing that these documents were submitted on April 3, 2002. Applicants respectfully request that the Examiner indicate that these references have been considered.

Rejection under 35 U.S.C. § 102

The Office rejected claims 1-4 and 7-9 under 35 U.S.C. § 102(b) for the reasons set forth in the Office Action mailed 02/07/2006. The Office stated that "Palomäki teaches the measurement of L1 plus L2 by taking an absorbance (page 57, column 2, paragraph 5) measurement as recited in the alternative limitation of the claim." (Final Office Action at ¶ 6). For the reasons discussed below, Applicants traverse the rejection and respectfully disagree with the Office's assertions regarding the teachings of *Palomäki*.

Applicants' claim 1 reads as follows:

1. A method for detecting an analyte A in a sample, comprising:

incubating an incubation mixture comprising a sample with an analyte A-specific binding partner R1, which is associated with a solid phase, an analyte A-specific binding partner R2, which is associated with a label L1, and an analyte A-specific binding partner R3, which is associated with a label L2, wherein saturation of analyte A-binding sites of the binding partner R2 takes place at a) a higher analyte A concentration, b) at a later time in the incubation, or c) at a higher analyte A concentration and at a later time in the incubation, than does saturation of analyte A-binding sites of the binding partner R3; and

determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal, or determining the L1-dependent measurement signal using a different measurement method than used to determine the L2-dependent measurement signal or the L1 plus L2-dependent measurement signal.

A restriction requirement was set forth on 02/02/05 and Applicants selected group 1 which included the limitation "L1-dependent measurement signal is determined at different times from L2 dependent measurement signal or L1 plus L2 dependent measurement signal".

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131. Contrary to the Office's assertion, *Palomäki* fails to teach the measurement limitations recited in independent claim 1. Specifically, *Palomäki* fails to teach "determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal".

Palomäki teaches the taking of a single absorbance measurement after the conjugate incubation and washing steps. The Office stated that "a separate

measurement was taken at optimal concentration when the HRP-Pab-HbsAg was used alone or simultaneous with diluted HRP-Mab2-HbsAg in the assay.” (Office Action of 02/07/06 at ¶ 5 (citations omitted).) An absorbance measurement when HRP-Pab-HbsAg is used alone or when HRP-Pab-HbsAg and HRP-Pab-HbsAg are used together, does not constitute “determining an L1-dependent measurement signal at a **different time** from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal,” as independent claim 1 recites. *Palomäki*, teaches the taking of a single measurement in two different assays. Applicants however, claim a method of taking at least two measurements, of the same assay, at different times.

For at least the reasons discussed above, the *Palomäki* reference does not teach all the elements of claim 1. Therefore, Applicants respectfully contend that *Palomäki* does not anticipate claims 1-4 and 7-9 and ask that this rejection be withdrawn.

Rejections under 35 U.S.C. § 103

The Office rejected dependent claims 5 and 6, independent claim 19, and its dependent claims 20-22 for the reasons set forth in the Office Action mailed 02/07/2006. The Office found that under 35 U.S.C. § 103, the claims were unpatentable over *Palomäki* in view of *Marquardt* (U.S. Patent No. 6,610,494). (Office Action of 02/07/06 at ¶ 7.) Applicants respectfully traverse.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) all claim limitations must be taught or suggested, (2) there must be some suggestion or motivation to modify the references or combine reference teachings, and (3) there must be a reasonable expectation of success. M.P.E.P. § 2143.03.

Applicants respectfully submit that the references provided by the Office do not teach or suggest all claim limitations.

Due to the dependency of claims 5-6, the limitations of claim 1 must be addressed when determining the alleged obviousness. For the reasons discussed above, *Palomäki* does not teach the measurement limitations of “determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal” as independent claim 1 recites. *Palomäki* teaches the taking of a single absorption measurement of the incubation mixture. Furthermore, *Palomäki* does not suggest the taking of more than one measurement signal at different times. *Marquardt*, on the other hand, teaches a method of detecting, via a solid-phase assay, the amount of biological activity and/or the quantity of a biologically active substance. *Marquardt* does not cure the defects of *Palomäki*. *Marquardt* does not teach a measurement strategy taking two separate measurements of the same sample at different times and the Examiner only relied on *Marquardt* for teaching the use of an XY binding pair labeling system.

Applicants respectfully submit that all of the limitations of claims 5 and 6 are not taught or suggested by the cited references. Therefore, the Office has not established a *prima facie* case of obviousness and the rejection of claims 5 and 6 should be withdrawn.

For many of the same reasons discussed above, *Palomäki* and *Marquardt* do not teach or suggest all the claim limitations of independent claim 19 and dependent claims 20-22. As discussed above, *Palomäki* fails to teach or suggest all of the measurement

limitations of claim 19, which are identical to the measurement limitations of claim 1.

Marquardt also fails to teach or suggest the measurement limitations of claim 19.

Specifically, neither *Palomäki* nor *Marquardt* teach the taking of two separate measurements of the same sample at different times and therefore, *Marquardt* can not cure the defects of *Palomäki*. Accordingly, *Palomäki* in view of *Marquardt* does not render Applicants' claim 19 obvious. Nor do these references make obvious the more narrow limitations of claims 20-22. Applicants respectfully request that this rejection be withdrawn.

The Office also rejected claims 10-15 under 35 U.S.C. § 103, for the reasons set forth in the Office Action mailed 12/07/2006. The Office found claims 10-15 unpatentable over *Palomäki* in view of *Cragle* (U.S. Patent No. 4,590,169). (Office Action of 02/07/06 at ¶ 8.) Specifically, the Office stated that *Cragle* teaches "that binding entities use particles for direct particle agglutination assays, wherein the particles become aggregated if the antigen is in the sample and this protocol can be performed in one step." (Office Action of 02/07/06 at ¶ 8.)

Applicants traverse this rejection. *Palomäki* and *Cragle* do not teach or suggest all the limitations of claims 10-15. Due to the dependency of claims 10-15, the limitations of claim 1 must be addressed when determining the alleged obviousness. For the reasons discussed above, *Palomäki* does not teach or suggest the measurement claim limitations of "determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal," as independent claim 1 recites.

These deficiencies of *Palomäki* that fail to teach or make obvious Applicants' invention cannot be found within the four corners of *Cragle*. The Examiner relies on *Cragle* for teaching the use of microparticles in a suspendable solid phase. *Cragle* does not teach or even suggest "determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal," as independent claim 1 recites. *Palomäki* and *Cragle*, as demonstrated above, fail to teach or suggest all the limitations of Applicants' claims 10-15. Therefore, Applicants respectfully request that this obviousness rejection be withdrawn.

The Office also rejected claims 16 and 17 under 35 U.S.C. § 103 for the reasons set forth in the Office Action mailed 12/07/2006. The Office found the claims unpatentable over *Palomäki* in view of *Pitner* (U.S. Patent No. 5,641,629). Specifically, the Office stated that *Pitner* teaches "that energy transfer techniques offers a sensitive and simple method of measuring the binding of specific analytes or target molecules." (Office Action of 02/07/06 at ¶ 9.)

Applicants traverse this rejection. *Palomäki* and *Pitner* do not teach or suggest all the limitations of claims 16 and 17. Due to the dependency of claims 16 and 17, the limitations of claim 1 must be addressed when determining the alleged obviousness. For reasons discussed above, *Palomäki* does not teach or even suggest Applicants' claim limitations of "determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal," as independent claim 1 recites.

These deficiencies of *Palomäki* that fail to teach or make obvious Applicants' invention cannot be found within the four corners of *Pitner*. The Examiner relies on *Pitner* for "its teaching of energy transfer assays which are known in the art to detect binding events." (Final Office Action at ¶10) *Pitner*, does not teach or even suggest "determining an L1-dependent measurement signal at a different time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal," as claim 1 requires. *Palomäki* and *Pitner*, as demonstrated above, fail to teach or suggest all the limitations of Applicants' claims 16 and 17. Therefore, Applicants respectfully request that this obviousness rejection be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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CPE/SJH

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: Carsten SCHELP et al.

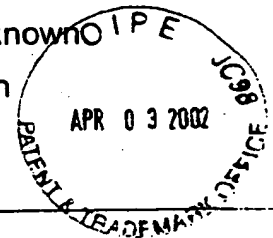
Serial No.: 10/024,258

Group Art Unit: Unknown

Filed: December 21, 2001

Examiner: Unknown

For: DETECTION METHODS



1. Information Disclosure Statement
2. PTO-1449 form and 31 documents cited therein
3. Recordation Form Cover Sheet with executed Assignment
4. Check no. 059226 in the amount of \$40.00 (recordation fee)

Dated: April 3, 2002

Docket No.: 05552.1450-00000

(Due Date: 03/21/02)

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